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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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01/16/2001

Colin C. Davis

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EXAMINER

ALI, SHUMAYA B

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

10/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/761,287	DAVIS, COLIN C.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/1/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

In response to the office action mailed on 5/1/07, no amendment to the claims is made. Claims 1-6 were previously withdrawn. Currently, claims 1-23 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson et al. US 5,487,378.

As to claims 7-16, Robertson lacks the detailed steps cited in claims 7-16. Robertson however teaches an inhaler with structures that are required **(see rejection cited for claims 17-23)** to perform the method steps cited in claims 7-16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the claimed method steps through the use of Robertson's inhaler.

As to claim 17, Robertson discloses an inhaler, comprising: a body (**fig.4a, 52**) including a mouthpiece (see **"inhaler device for dispensing droplets of liquid medicament to a patient comprising a body having a mouthpiece...and a reservoir of liquid medicament in**

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communication with an aerosol generator, the aerosol generator comprising a chamber for liquid medicament and a nozzle arrangement comprising a plurality of orifices in fluid flow relationship with liquid medicament in said chamber” in col.2, lines 50-55); a supply of liquid (fig.1a, 1) carried in the body; a drop generator (see figs 3 and 4a) head mounted to the body in fluid communication with the liquid. Robertson however lacks a plurality of chambers. However knowing Robertson teaches one chamber, providing multiple chambers only involves routine skill in the art. Robertson further teaches each chamber receiving some of the liquid and opening to surrounding air (see figs.3 and 4a). Robertson further teaches a plurality of heat transducer (fig.4a, 58,60), one heat transducer residing in each chamber and controllable for instantaneously heating the liquid (vibration and confined space, i.e., at the nozzle end, see fig.4a, would allow heat transfer between molecules of the liquid and walls of the confined space where liquid is being stored. This process can cause liquid to produce heat and walls of the confined space to trap heat to further heat up the liquid. Furthermore, heat applied to the liquid by heat transducers to generate droplet sizes allows liquid to be heated as well), the chamber by an amount sufficient to produce a vapor bubble (col.6, lines 25-57) in the chamber for propelling the liquid from the chamber in the form of droplets, each droplet having a volume of less than 100 femtoliters (see col.3, lines 14-45), thereby to facilitates aerosol delivery of the droplets to the alveoli of a user of the mouthpiece.

As to claim 18, Robertson discloses the inhaler of claim 17 wherein each heat transducer have an area (touching 56 in fig.4a) and is mounted adjacent to an upper surface in the chamber (fig.4a, 52), and the drop generator includes an orifice opening (fig.4b, 50) through an outer surface of the drop generator head, and wherein the distance between the upper surface

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of the chamber and the outer surface is less than 0.75 times the square root of the heat transducer residing in that chamber (see **fig.4a**).

As to **claim 19**, **Robertson** discloses an inhaler, comprising: a body (**fig.4a, 52**), a supply of medicinal liquid carried in the body (see “**inhaler device for dispensing droplets of liquid medicament to a patient comprising a body having a mouthpiece...and a reservoir of liquid medicament in communication with an aerosol generator, the aerosol generator comprising a chamber for liquid medicament and a nozzle arrangement comprising a plurality of orifices in fluid flow relationship with liquid medicament in said chamber**” in col.2, lines 50-55);; a drop generator head (see **figs 3 and 4a**) mounted to the body in fluid communication with the medicinal liquid. **Robertson** however lacks a plurality of chambers. However knowing **Robertson** teaches one chamber, providing multiple chambers only involves routine skill in the art. **Robertson** further teaches each chamber receiving some of the medicinal liquid and each chamber having an orifice (**fig.4b, 50**); and a plurality of heat transducers transducer (**fig.4a, 58,60**), one heat transducer being associated with each chamber and controlled for instantaneously heating the medicinal liquid (**vibration and confined space, i.e., at the nozzle end, see fig.4a, would allow heat transfer between molecules of the liquid and walls of the confined space where liquid is being stored. This process can cause liquid to produce heat and walls of the confined space to trap heat to further heat up the liquid.** Furthermore, heat applied to the liquid by heat transducers to generate droplet sizes allows liquid to be heated as well) in the chamber by an amount sufficient to produce a vapor bubble (result in heating the liquid) in the chamber for propelling medicinal liquid though the orifice

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with force sufficient for separating the propelled liquid into two or more droplets for inhalation by a user (col.2, lines 45-67, col.3, lines 1-39).

As to claim 20, Robertson discloses the inhaler of claim 19 wherein the liquid propelled from a single chamber is directed through a single orifice (fig.4a, 70) to separate into two or more discrete droplets (fig.4a, 72) traveling in different trajectories.

As to claim 21, Robertson discloses the inhaler of claim 19 wherein the liquid propelled from a single chamber is directed through at least two orifices (fig.4a, 72, and orifice through 50) that separate the liquid into two or more discrete droplets (fig.4a, 72.)

As to claim 22, Robertson discloses the inhaler of claim 19 further comprising a mouthpiece connected to the body and within which the droplets are introduced for inhalation by a user (see “inhaler device for dispensing droplets of liquid medicament to a patient comprising a body having a mouthpiece” in col.2, lines 50 and 51).

As to claim 23, Robertson discloses the inhaler of claim 19 further comprising a recess mechanism (fig.4a, 70/ recess through 50) for directing gas to the propelled droplets thereby to entrain the droplets in the gas.

Response to Arguments

Applicant's arguments filed on 8/1/07 have been fully considered but they are not persuasive. On page 7, lines 25-28 of the remark filed on 8/1/07, Applicant argued that Robertson does not teach heating the liquid, and on page 8, lines 10-13, Applicant further argued, “Robertson pressurizes the liquid with a piezo-electric element. Using heat on liquid to generate small drop is clearly different than using pressure on liquid to generate small drops”.

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These arguments are not well taken because Robertson teaches the liquid is pressurized, thus agitation or vibration of liquid can cause individual molecules of the liquid to bounce back at one another, which can result in heat transfer between molecules. Thus, can cause liquid to be heated to certain degrees. Furthermore, molecules being pressured and vibrated in a small area, i.e., at the nozzle end (see fig.4a) would likely to expedite heat production because now the heat can be transferred between the molecules as well as the walls of the container where molecules/liquid is being stored. This process can allow container to become warm and trap heat, which can further help to heat up the liquid. Furthermore, there is no structure in Robertson that will prevent one to increase vibration time and frequency such to produce extensive vibration, hence heat that caused liquid to boil and produce vapor. As Applicant noted, Robertson teaches heat transducer and heat is used on the liquid to generate small drops. Thus, as long as the heat is applied to the liquid using Robertson's device, one of ordinary skill in the art can carry out claimed method steps requiring "instantaneously heating the liquid". Thus, Robertson teaches a device which has structures that is fully capable of heating the liquid. Thus, rejection to claims using Robertson is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

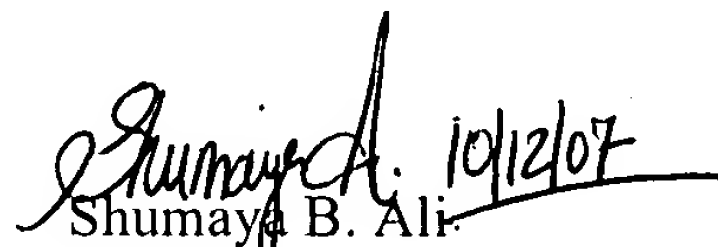
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali
Examiner
Art Unit 3771


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10/12/07